

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Katsumi AOYAGI et al.  
Title: METHOD OF DETECTING HEPATITIS C VIRUS  
Appl. No.: 10/577,853  
International Filing Date: 10/28/2004  
371(c) Date: 10/17/07  
Examiner: Michelle S. Horning  
Art Unit: 1648  
Conf. No.: 4864

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

Atty. Dkt. No. 053466-0416

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing of a first Office action after the filing of a Request for Continued Examination under §1.114.

**RELEVANCE OF EACH DOCUMENT**

Any document listed on the attached PTO/SB/08 was cited as being relevant in a Notice of Opposition filed against the corresponding European patent on July 27, 2011, a copy of which is submitted herewith. An English-language abstract and counterpart of foreign-language Document F3 is provided.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Although Applicant believes that no fee is required, the Commissioner is hereby authorized to charge any additional fees which may be due to Deposit Account No. 19-0741.

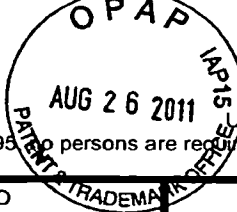
Respectfully submitted,

Date AUG 26 2011

By 

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Approved for use through 03/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

Date Submitted: August 26, 2011

(use as many sheets as necessary)

Sheet 1 of 1

**Complete if Known**

Application Number	10/577,853
Filing Date	10/28/2004
First Named Inventor	Katsumi Aoyagi
Art Unit	1648
Examiner Name	Michelle S. Horning
Attorney Docket Number	053466-0416

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
/MH/	F1	4,703,001 A	10/27/1987	Vodian et al.	
/MH/	F2	5,306,622 A	04/26/1994	Mangold, Dieter	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
/MH/	F3	EP 0 296 336 B1	12/28/1988	Boehringer Mannheim GmbH		A✓
/MH/	F4	EP 1 021 723 B1	07/26/2000	Novartis Vaccines and Diagnostics, Inc.		

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
/MH/	F5	NISHANIAN et al., "A Simple Method for Improved Assay Demonstrates that HIV p24 Antigen is Present as Immune Complexes in Most Sera from HIV-Infected Individuals," Journal of Infectious Diseases, 1990, 162:21-28	
/MH/	F6	PACE et al., "Optimization of Immunohistochemical Reactions," Immunohistochemical Staining Methods, 2009, Chapter 16, 109-114.	
	F7	SIGMA, "Trizma®HCl Specification Comparison," found July 1, 2011, 1 page.	

Examiner  
Signature

/Michelle Horning/

Date  
Considered

10/02/2011

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MH/